

Question Text	Author Response	Custom Submission Question ID
Is this a clinical trial? This is defined as any clinical research in which patients were randomized into two treatment groups OR in which patients were followed prospectively to compare two different treatments.	Yes -	56
Please enter the registry name and trial number. Per our Instructions for Authors , all clinical trials must be registered in a public trials registry such as https://www.clinicaltrials.gov/ .	https://clinicaltrials.gov/ct2/show/NCT01868425	57
Please complete the following questions in accordance with the International Committee of Medical Journal Editors' recommendations on data sharing in clinical trials (guidelines and examples are available here). Will individual participant data be available (including data dictionaries)?	Yes	58
What data in particular will be shared? (Examples include all individual participant data after deidentification, only participant data that underlies the results, or not available.)	All of the individual participant data collected during the trial, after deidentification.	59
What other documents will be available?	Study Protocol including statistical analysis plan, Informed Consent Form	60